



**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-18-0666; Docket No. CDC-2018-0042]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Healthcare Safety Network (NHSN). NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2018-0042 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

#### Proposed Project

National Healthcare Safety Network (NHSN) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship. The data collected will be used to inform and detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. NHSN is comprised of six components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility, Outpatient Procedure, and Dialysis.

Changes were made to 33 data collection facility surveys with this new ICR. CDC revised three annual facility surveys for

the Patient Safety component for Hospitals, Long-Term Acute Care Facilities, and Inpatient Rehabilitation Facilities. CDC's revisions clarify the reporting requirements for the data collected on fungal testing, facility locations, and laboratory testing locations. Additionally, corresponding response options for these questions have been revised to include updated testing methods used by facilities to capture current HAI specific data specification requirements for NHSN. New required questions have been added to all Patient Safety component surveys. The new questions are designed to provide data on surveillance processes, policies, and standards that are used by reporting facilities to ensure that when an event is detected, the facility has the appropriate mechanism to conduct complete reporting. The Hospital Annual Survey added new required questions to provide data about neonatal antimicrobial stewardship practices because the focus of stewardship efforts in neonatology differ from the focus in adult and pediatric practice. Questions were removed and replaced on all three Patient Safety surveys to align better with the Core Elements of Hospital Antibiotic Stewardship Programs specified by CDC. The Core Elements defined by CDC are part of broad-based efforts by CDC and its healthcare and public health partners to combat the threat of antibiotic-resistant bacteria. The new Antibiotic Stewardship Program questions will provide additional data about

operational features of the programs that hospitals have implemented, which in turn will enable CDC and its healthcare and public health partners to target their efforts to help invigorate and extend antibiotic stewardship.

CDC is introducing a new optional survey form that is designed to be completed by state and local health departments that participate in HAI surveillance and prevention activities. This new form will provide data on legal and regulatory requirements that are pertinent to HAI reporting. CDC plans to include data the health department survey in its annual National and State Healthcare-Associated Infection Progress Report. The report helps identify the progress in HAI surveillance and prevention at the state and national levels. Data about the extent to which state health departments have validated HAI data that healthcare facilities in their jurisdiction report to NHSN and the extent of state and local health department HAI reporting requirements are important data for users of CDC's HAI Progress Report to consider when they are reviewing and interpreting data in the report.

NHSN now includes a ventilator-associated event available for NICU locations, which requires additional denominator reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data by updating the corresponding surveys. The Pediatric Ventilator-Associated Event

(PedVAE) was removed from the survey because a single algorithm is used to detect PedVAE events.

NHSN has made updates to the Antimicrobial Use and Resistance (AUR) data collection tools for the purposes of monitoring additional microorganisms and their antimicrobial susceptibility profiles. Use of these updates in AUR surveillance will provide important additional data for clinical and public health responses to mounting antibiotic resistance problems.

The Long-term Care Facility Component (LTCF) will be updating three forms, two of which will include an update for facilities to document the "CDI treatment start" variable. Early CDI reporting data from nursing homes has shown exceptionally low event rates for many reporting facilities (e.g., zero events for six or more months). Since current CDI event detection is based on presence of a positive laboratory specimen, variability in the use of diagnostic testing as part of CDI management will have direct impact on the estimate of CDI burden in a facility (e.g., empiric treatment for CDI without confirmatory testing may result in the appearance of low disease burden). In order to determine whether low CDI event rates might be due to empiric CDI treatment practices, a new process measure will be incorporated into the monthly summary data on CDI for LTCFs. This measure, called "CDI treatment starts," will allow

providers to capture the number of residents started on antibiotic treatment for CDI that month based on clinical decisions (i.e., even those without a positive CDI test). This process measure should provide data on clinically-treated CDI in order to inform our understanding of CDI management practices and serve as a proxy for CDI burden in nursing homes.

Overall, minor revisions have been made to a total of 33 forms within the package to clarify and/or update surveillance definitions, increase or decrease the number of reporting facilities, and add new forms.

The previously approved NHSN package included 72 individual collection forms; the current revision request includes a total of 73 forms. The reporting burden will decrease by 109,745 hours, for a total of 5,393,725 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Healthcare facility	57.100 NHSN Registration Form	2,000	1	5/60	167
	57.101 Facility Contact Information	2,000	1	10/60	333
	57.103 Patient Safety Component-- Annual Hospital Survey	6,000	1	1.17	7,500

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	57.105 Group Contact Information	1,000	1	5/60	83
	57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60	18,000
	57.108 Primary Bloodstream Infection (BSI)	6,000	44	33/60	145,200
	57.111 Pneumonia (PNEU)	1,800	72	30/60	64,800
	57.112 Ventilator-Associated Event	6,000	144	28/60	403,200
	57.113 Pediatric Ventilator-Associated Event (PedVAE)	100	120	30/60	6,000
	57.114 Urinary Tract Infection (UTI)	6,000	40	20/60	80,000
	57.115 Custom Event	600	91	35/60	31,850
	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	6,000	12	4	288,000
	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	2,000	9	5.03	90,600
	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	6,000	60	5.03	1,812,000
	57.120 Surgical	6,000	36	35/60	

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	Site Infection (SSI)				126,000
	57.121 Denominator for Procedure	6,000	540	10/60	540,000
	57.122 HAI Progress Report State Health Department Survey	55	1	45/60	41
	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,000	12	5/60	1,000
	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	2,000	12	5/60	2,000
	57.125 Central Line Insertion Practices Adherence Monitoring	100	100	25/60	4,167
	57.126 MDRO or CDI Infection Form	6,000	72	30/60	216,000
	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	6,000	24	15/60	36,000
	57.128 Laboratory-identified MDRO or CDI Event	6,000	240	20/60	480,000
	57.129 Adult	50	250	25/60	

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	Sepsis				5,208
	57.137 Long-Term Care Facility Component - Annual Facility Survey	2,600	1	2	5,200
	57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,600	12	20/60	10,400
	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	20/60	10,400
	57.140 Urinary Tract Infection (UTI) for LTCF	2,600	14	35/60	18,200
	57.141 Monthly Reporting Plan for LTCF	2,600	12	5/60	2,600
	57.142 Denominators for LTCF Locations	2,600	12	4.17	130,000
	57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	5/60	2,600
	57.150 LTAC Annual Survey	400	1	1.17	467
	57.151 Rehab Annual Survey	1,000	1	1.17	1,167
	57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	8	400
	57.203 Healthcare	19,500	1	5/60	

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	Personnel Safety Monthly Reporting Plan				1,625
	57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333
	57.205 Exposure to Blood/Body Fluids	50	50	1	2,500
	57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375
	57.207 Follow-Up Laboratory Testing	50	50	15/60	625
	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417
	57.300 Hemovigilance Module Annual Survey	500	1	1.42	708
	57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1/60	100
	57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	1.17	7,000
	57.305 Hemovigilance Incident	500	10	10/60	833
	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	200	1	35/60	117
	57.307	500	4	20/60	

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction				667
	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	20/60	667
	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60	167
	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60	333
	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	20/60	667
	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	20/60	167
	57.313 Hemovigilance Adverse Reaction - Infection	500	1	20/60	167

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	20/60	167
	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	20/60	167
	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	20/60	167
	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	20/60	167
	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	20/60	333
	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	20/60	167
	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	20/60	167

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	57.400 Outpatient Procedure Component—Annual Facility Survey	5,000	1	10/60	417
	57.401 Outpatient Procedure Component - Monthly Reporting Plan	5,000	12	20/60	15,000
	57.402 Outpatient Procedure Component Same Day Outcome Measures	1,200	25	40/60	20,000
	57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	1,200	12	40/60	9,600
	57.404 Outpatient Procedure Component - SSI Denominator	5,000	540	10/60	450,000
	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	5,000	36	35/60	105,000
	57.500 Outpatient Dialysis Center Practices Survey	7,000	1	2.12	14,817
	57.501 Dialysis Monthly Reporting Plan	7,000	12	5/60	7,000
	57.502 Dialysis Event	7,000	60	25/60	175,000
	57.503 Denominator for Outpatient Dialysis	7,000	12	10/60	14,000

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	2,000	12	1.42	17,000
	57.505 Dialysis Patient Influenza Vaccination	325	75	10/60	4,063
	57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60	271
	57.507 Home Dialysis Center Practices Survey	350	1	30/60	175
Total					5,393,725

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